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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,502	12/17/2001	Kelly Moran	BJA219A	4304

7590 10/19/2005
BOLESH J. SKUTNIK PhD, JD
515 Shaker Road
East Longmeadow, MA 01028

EXAMINER

SCHAETZLE, KENNEDY

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/023,502	MORAN, KELLY	
	Examiner	Art Unit	
	Kennedy Schaetzle	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,9,10,12,14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,9,10,12,14 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 28, 2005 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 2, 4, 12, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff (Pat. No. 4,287,554).

Regarding claim 1, Wolff discloses that the electromagnetic radiation produced by his device may be employed to treat acne, psoriasis, or other skin related disorders. Wolff further discloses that wavelengths within the range from 193 nm to 10.6 micrometers are most effective in treating psoriasis, acne and other skin irregularities or diseases (col. 1, lines 49-57).

While the system of Wolff does not disclose the use of coherent radiation applied with at least one optical fiber, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to utilize such an arrangement because the applicant has not disclosed that coherent light applied with an optical fiber provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with non-coherent light applied by a lamp because, the

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applicant admits that such light is effective in treating wounds of the type covered by the invention (see page 6, lines 7, 8 and 22-25). The healing process is clearly not dependent upon the particular means used to transmit the radiation to the wound – rather the energy content, wavelength and treatment time. Any artisan looking to direct the radiation to a specific limited affected area of the body would have therefore considered the use of coherent laser radiation as a matter of obvious design. See *Ex parte Clapp*, 224 USPQ 972, 973 (Bd. Pat. App. & Int. 1985), *In re Soli*, 317, F. 2d 941, 947, 137 USPQ 797, 801 (CCPA 1963) and MPEP §2144.02.

As for the treatment of stage 1-2 wounds, please refer to the arguments presented in the prior Office Action under par. 8.

Regarding claim 2, the examiner considers the power density of the Wolff device to be at least 1 W/cm^2 given the effects produced by the application of radiation energy. Since Wolff discloses that skin disorders such as acne and psoriasis may be effectively treated, the power density must be of a sufficient magnitude in order for any beneficial results to occur. Such a magnitude would necessarily be of a similar strength to the applicant's device since it also treats the same conditions by electromagnetic radiation of a similar wavelength. Concerning the exposure times, Wolff discloses that treatment times may correspond to the performance of mundane acts such as brushing ones teeth or combing one's hair. The examiner considers such acts to reasonably fall within the 1 second to 3 minute exposure time.

Regarding claim 12, the examiner considers the radiation produced by the Wolff device to be inherently capable of eradicating bacteria and viral bodies.

Regarding claim 15, similar comments made in the rejection of claim 1 apply here as well. Concerning the use of radiation with a wavelength of 930 nm, those of ordinary skill in the art would have considered the exact wavelength of operation to be an application dependent parameter. The particular ailment being treated and the condition of the patient would necessarily dictate the most appropriate wavelength for the situation at hand, with routine experimentation determining the most effective treatment wavelengths for any given disease and patient type. The applicant further gives no criticality to the use of 930 nm radiation. The applicant has not disclosed that

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930 nm radiation provides an advantage, is used for a particular purpose, or solves a stated problem. The applicant to the contrary discloses that wavelengths in the range disclosed by Wolff are effective in treating wounds. One would therefore expect the invention to work equally well within the range of wavelengths disclosed.

4. Claims 1, 2, 4, 12, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehurst (Pat. No. 6,461,866).

Whitehurst discloses the use of a non-coherent, non-ablative light source useful in the cosmetic treatment of dermatological conditions such as portwine stains, psoriasis, etc. (col. 3, lines 32-46) with an output intensity of generally greater than 1 W/cm² (col. 1, lines 65-67), which can be focused and delivered via at least one optical fiber (col. 2, lines 4-7) at wavelengths in the range of 193 nm to 3 micrometers (col. 3, lines 47-53) and treatment times of 0-9999 seconds (col. 4, lines 29-36).

While Whitehurst employs non-coherent light in the practice of his invention instead of coherent light (i.e., laser) due to the disadvantages listed in col. 1, lines 12-32 (e.g., high cost, size, power consumption, sophistication, etc.), it is well known in the art that coherent light may be used effectively despite its cost, size and complexity. Whether a system is more costly to purchase, takes up more space, or requires a higher skill level to operate does not negate the fact that such a system can be effective to treat skin disorders such as discussed by Whitehurst. By analogy, a diamond tipped jackhammer may be more costly to purchase and thus not recommended for use, yet such a tool would hardly be considered novel or unobvious given the known properties of diamonds. Likewise, given the known effectiveness of coherent light in treating dermatological disorders, those of ordinary skill in the art would have considered the use of a coherent light source such as a laser to be obvious for the healing of stage one and stage two wounds.

Again, regarding the treatment of stage 1-2 wounds, please refer to the examiner's arguments presented under paragraph 8 of the previous Office Action.

Regarding claim 15, similar comments made in the rejection of claim 1 apply here as well. Concerning the use of radiation with a wavelength of 930 nm, those of ordinary skill in the art would have considered the exact wavelength of operation to be

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an application dependent parameter. The Whitehurst invention is operative at 930 nm as cited above. The particular ailment being treated and the condition of the patient would necessarily dictate the most appropriate wavelength for the situation at hand, with routine experimentation determining the most effective treatment wavelengths for any given disease and patient type. The applicant further gives no criticality to the use of 930 nm radiation. The applicant has not disclosed that 930 nm radiation provides an advantage, is used for a particular purpose, or solves a stated problem.

5. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehurst as applied to claims 1, 2, 4, 12, 14 and 15 above, and further in view of Talmore (Pat. No. 5,344,433).

Whitehurst does not appear to explicitly discuss the average power of the radiation energy produced by the 300 W Xenon short arc lamp. Talmore, however, discloses the use of an identical light source and states that the lamp provides a light beam with an output of 1W (col. 4, lines 5-13). It would appear that the particular level of radiation power desired would depend upon the application at hand and the particular skin condition being treated. Lacking any criticality by the applicant in regards to providing a 1W output or a 5 to 10 W output, those of ordinary skill in the art would have seen the particular power level to be an obvious matter of design dependent upon the conditions of the particular wound being treated.

Conclusion

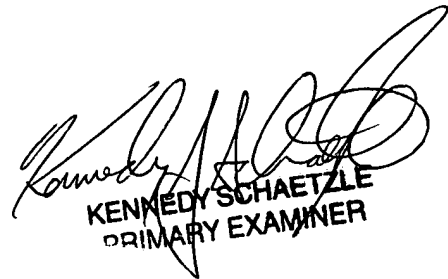
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on M-F at 571 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
October 16, 2005



KENNEDY SCHAEZLE
PRIMARY EXAMINER